UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

August 1, 2002

MEMORANDUM:

Subject: Efficacy Review EPA Reg. No.675-55 Lysol Brand Disinfectant S.A. Cleaner
DP Barcode 284078
Case No. 062161

From: Nancy Whyte, Microbiologist NEW
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Thru: Emily Mitchell, M.S., Team Leader Emily Mitchell 8/27/12
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Thru: Michele E. Wingfield, Chief
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Applicant: Reckitt Benckiser Inc.
1655 Valley Road
Wayne, NJ 07474

Formulation Label:

Active Ingredient(s)	% by wt.
Citric acid	2.50%
Other ingredients	97.50%
Total	100.00%

I. Background:

This is a cleaner, deodorizer, and disinfectant product which is used on hard, non-porous surfaces in bathrooms in homes, schools, healthcare facilities and public places. The registrant has submitted additional data requested by the Agency in December 2001 following

the last submission. The data requested, verification of the antibiotic resistance of the two organisms for which label claims were made, has been submitted in one document, MRID No. 456874-01. The data in the document support the previously submitted data in MRID Nos. 454311-02 and -03. The organisms which had been tested for effectiveness of the product were Methicillin resistant *Staphylococcus aureus (MRSA)* , and Vancomycin resistant *Enterococcus faecalis (VRE).* Both organisms had been obtained from the American Type Culture Collection (ATCC 33592 and ATCC 51299) and had been entered in their collections as specifically resistant to methicillin and vancomycin, respectively.

II. **Summary of Data Submitted:**

Following receipt of the Agency letter dated December 10, 2001 the registrant requested from the original efficacy testing facility AppTec Laboratory Services, St. Paul, MN the documentation necessary to reply to the Agency. A review of resistance profiles over a period from 1996 to 2002 was completed, which demonstrated that the resistance profiles of these organisms was highly conserved. Periodically, the laboratory sends subcultures of these organisms to Fairview University Medical Center's Diagnostic Microbiology Laboratory for reevaluation of the antibiotic resistant profile. The National Committee for Clinical Laboratory Standards (NCCLS) methodologies and quality control are used by the laboratory to conduct the antibiotic susceptibility testing. An appropriate method for the historical strain being tested is selected from the following manual procedures: Brain Heart Infusion screen, *Etest,* Kirby-Bauer Disc Diffusion and Macro Broth Tube dilution, or an automated method to determine the Minimum Inhibitory Concentration (MIC) using bioMerieux Vitek. The lack of differences between the test dates shows that there is no impact from different slant preparations for each test date, different transfer frequencies prior to conducting the AOAC study, and different technologists conducting the tests. The Association of Official Analytical Chemists (AOAC) study on the MRSA strain was completed by February 2000 so the results of the review demonstrate that resistance profile was conserved prior to and after the AOAC test.

The previous efficacy review also requested verification that the product designated Formula 592-063 in the efficacy study was in fact the same as the basic Lysol Brand Disinfectant S.A. Cleaner EPA Reg. No. 675-55. The letter enclosed in this submission states that they are the same product.

A further clarification of the identity of the Rotavirus used in the efficacy testing reported in the previous submission was also requested by the Agency. The registrant states that the organism *"Rotavirus, Strain WA"* was a clinical isolate obtained from the University of Ottowa and did not have an ATCC number.

II. **Recommendations and Comments:**

1. The data submitted by the registrant to substantiate the conservation of the resistance profiles confirms that the product is effective against *Staphylococcus aureus* (MRSA) ATCC 333592 and *Enterococcus faecalis* (VRE) ATCC 51299 are acceptable, and the claims for these organisms may be added to the label.

2. The statements to confirm the identity of Rotavirus, Strain WA and to verify that the product tested using the designation Formula 592-063 is the same as Lysol Brand Disinfectant S.A. Cleaner are accepted. In future submissions, the registrant must be consistent in the designation of the product being tested. The final report must verify that the testing was done on the product bearing the EPA Registration Number.

3. The identity of the Rotavirus,Strain WA is noted as a clinical isolate from the University of Ottawa.